U.S.S.N.: 09/766,362 Filed: January 19, 2001

RESPONSE TO OFFICE ACTION

### The claimed invention

Claims 1-19 are drawn to a composition for the nasal administration of a drug, a device for delivering and a method for using the same, the drug being in a dry powder form having an average particle size of between 10 and 20 microns, in a dosage formulation suitable for administration to the nasal region. The critical aspect of the claims is the ability of the drug particles to be delivered to and remain in the nasal region, which requires the particles to have a size in the range of between 10 and 20 microns. If the particles have a size below 10 microns, the particles will pass the nasal region and go to the pulmonary system; if the particles have a size above 20 microns, the particles would not be delivered to the nasal region.

#### Hettche

Hettche describes a formulation of azelastine that is suitable for administration to the eye and/or nose (col. 1, lines 37-38). The formulation can be solutions, suspensions as well as oily solutions or suspensions, ointments, emulsions, creams, gels, dosage aerosols (col. 3, lines 26-28). In the case of powders, the concentration of azelasine base is 0.005 to 2 percent by weight relative to the solid carrier substances (col. 3, lines 37-39). The particle size for an insufflatable powder should not be greater than 20 microns (col. 5, lines 51-53). The carrier substances for solid powder formulation include sugars such as glocose, saccharose, lactose and fructose, starches or their derivatives, oligosaccharides such as dextrins, cyclodextrins and their derivatives, polyvinyl pyrrolidone, alginic acid, tylose, silicic acid, cellulose, cellulose derivatives, sugar alcohols such as mannitol or sorbitol, calcium carbonate, calcium phosphate (col. 5, lines 57-66). The examples describe various solution, aerosol, or ointment formulations for nasal or eye administration (Examples 1-4).

U.S.S.N.: 09/766,362 Filed: January 19, 2001

RESPONSE TO OFFICE ACTION

## Analysis

1. Hettche fails to provide an enabling disclosure for dry powder delivery to the nasal region

Contrary to the Examiner's assertion, Hettche does not disclose the critical particle size range required for nasal administration. The claims require the particle size to be between 10 to 20 microns. This range of particle size is necessary for the drug particles to be delivered to and remain at the nasal region. In contrast, Hettche only describes that, when azelastine is used in the form of a powder, the maximum particle size is 20 microns. Therefore, the particle size range described in Hettche is 0 to 20 microns. As discussed at p. 2, lines 20-23, the particle size range of between 10 to 20 microns is critical to cause the particles to be retained in the nasal range. It is well documented in the art of drug delivery that small particles will pass through the nasal region and deposit in the pulmonary region, e.g., lung (see, for example, Edwards et al., "Recent advances in pulmonary drug delivery using large, porous inhaled particles" in J Appl Physiol 85(2):379-85 (1998) (Review)). Therefore, while the particle size of Hettche will cause the particles to be delivered to the nasal region, there is no teaching in Hettche to cause the particles to be retained in the nasal region.

It is well established that, to be available as prior art, a reference has to provide an enabling disclosure. In re Hoeksema, 399 F.2d 269, 158 USPQ 596 (CCPA 1968); see also MPEP § 2121.01. Hettche is directed to liquid formulations for nasal delivery of azelastine. For example, claim 1 of Hettche is drawn to a method which comprises applying a medicament directly to nasal tissues or to the conjunctival sac of the eyes, which, to one of ordinary skill in the art, has to be in a liquid formulation. The examples describe different liquid formulations

APR. 10. 2002 5:42PM

U.S.S.N.: 09/766,362 Filed: January 19, 2001

RESPONSE TO OFFICE ACTION

using various thickening agents (see col. 6, line 6 to col. 7, line 46). In contrast, nowhere does Hettche describe formulations and the particle size range of 10 to 20 microns for delivering azelastine which will be retained in the nasal region (see *In re Wertheim*, 541 F.2d 257, 264, 191 USPQ 90 (CCPA 1976) (holding that where it is clear that the broad described range pertains to a different invention than narrower claimed range, then broader range does not describe narrower range for purpose of statute relating to specifications in application for patent). As such, Hettche certainly fails to disclose a powder formulation to be delivered to and remain in the nasal region.

# 2. Hettche fails to disclose the claimed dry powder with sufficient specificity

As discussed above, the size range described in Hettche is 0 to 20 microns. The recited particle size range, however, is the much narrower range, 10 to 20 microns, which, as discussed above, is critical for the particles to be delivered to and retained in the nasal region. Hettche also uses inert carrier materials such as sugars, starches, and celluloses. To one of ordinary skill in the art, these carrier materials do not have good air-dynamic properties, for example, quickly absorbing moisture, that would cause much difficulty to deliver the drug particles to the nasal region. Therefore, Hettche fails to describe the claimed subject matter with "sufficient specificity" so as to anticipate the claims (see MPEP § 2131.05; see also Ex parte Lee, 31 USPQ2d 1105 (Bd. Pat. App. & Inter. 1993)).

In summary, Hettche fails to anticipate claims 1-4, 6-11, 13-17 and 19 under 35 U.S.C. 102(b).

APR. 10. 2002 5:43PM HOLLAND & KNIGHT NO. 2452 P. 11

U.S.S.N.: 09/766,362 Filed: January 19, 2001

RESPONSE TO OFFICE ACTION

Rejections under 35 U.S.C. 103

Claims 5, 8, and 12 were rejected under 35 U.S.C. §103 as obvious over Hettche in view of U.S. Patent No. 5,352,461 to Feldstein et al. ("Feldstein"). The applicants respectfully traverse this rejection.

The critical aspect of the claims is that the dry powder having particle size in the range between 10 to 20 microns so that the drug particles can be delivered to and retain in the nasal region. As discussed above, Hettche fails to provide an enabling disclosure for drug particles to be delivered to and retain in the nasal region and therefore fails to anticipate the claimed formulation (see, In re Wertheim, 541 F.2d at 264). Feldstein describes a diketopiperazine drug delivery system in the form of microspheres encapsulating bioactive agents for topical, local or systemic parenteral, or enteral administration (col. 7, lines 9-11). Therefore, none of Hettche and Feldstein provide the motivation for one of ordinary skill in the art to make and use the claimed subject matter. Moreover, Feldstein teaches particles of between 0.1 to 10 microns (col. 3, lines 21-23), which, to one of ordinary skill in the art, would pass through the nasal region to the pulmonary system (see, Edwards et al., "Recent advances in pulmonary drug delivery using large, porous inhaled particles" in J Appl Physiol 85(2):379-85 (1998) (Review)). Therefore, neither Hettche nor Feldstein provide an enabling disclosure of a dry powder formulation for nasal delivery, which requires the powder to stay in the nasal region. As such, even if Hettche and/or Feldstein provide one of ordinary skill in the art to make and use dry powder formulations for nasal administration, one still cannot have a reasonable expectation of success of the claimed subject matter, which causes the drug particles to be delivered to and retain in the nasal region. As such, claims 5, 8, and 12 are not obvious over Hettche in view of Feldstein under 35 U.S.C.

U.S.S.N.: 09/766,362 Filed: January 19, 2001

RESPONSE TO OFFICE ACTION

103 (see *Hodosh v. Block Drug Co. Inc.*, 786 F.2d 1136, 1143 n.5, 229 USPQ 182 n.5 (Fed. Cir. 1986; see also MPEP § 2141).

Allowance of claims 1-19 is therefore earnestly solicited. A copy of the claims as pending is attached as appendix for the Examiner's convenience.

Respectfully submitted,

Zhaoyang Li Reg. No. 46,872

Dated: April 10, 2002 Holland & Knight LLP One Atlantic Center, Suite 2000 1201 W. Peachtree Street Atlanta, GA 30309-3400 (404) 817 - 8473 (404) 817 - 8588 (fax) APR. 10. 2002

U.S.S.N.: 09/766,362 Filed: January 19, 2001

RESPONSE TO OFFICE ACTION

# CERTIFICATE OF FACSIMILE TRANSMISSION

I hereby certify that the Response to Office Action referred to as being attached or enclosed, has been sent via facsimile transmission is to the Assistant Commissioner for Patents, Washington, D.C. 20231.

Date:

April 10, 2002

7

U.S.S.N.: 09/766,362 Filed: January 19, 2001 RESPONSE TO OFFICE ACTION

### APPENDIX: Claims as Pending

- A composition for the nasal administration of a drug to a patient comprising
  a drug in a dry powder form having an average particle size of between 10 and 20
  microns, in a dosage formulation suitable for administration to the nasal region.
- 2. The composition of claim 1 wherein the drug is selected from the group consisting of antihistamine, vasoconstrictors, antiinflammatories and analgesics.
- 3. The composition of claim 2 wherein the antihistamine is selected from the group consisting of chlorpheniramine and azelastine.
  - 4. The composition of claim 1 wherein the drug is formulated in a polymeric carrier.
- 5. The composition of claim 1 wherein the <u>drug</u> is formulated in a diketopiperazine formulation.
- The composition of claim 1 wherein the dry powder formulation consists essentially
  of drug.
  - 7. A drug delivery device for nasal administration comprising
- a drug in a dry powder form having an average particle size of between 10 and 20 microns, in a dosage formulation for administration to the nasal region, and
  - a device for delivering a measured dose of the drug to the nasal mucosa.
  - 8. The device of claim 7 wherein the device is a nasal insufflator.
- 9. The device of claim 7 wherein the drug is selected from the group consisting of antihistamine, vasoconstrictors, antiinflammatories and analgesics.
- 10. The device of claim 7 wherein the antihistamine is selected from the group consisting of chlorpheniramine and azelastine.
  - 11. The device of claim 7 wherein the drug is formulated in a polymeric carrier.
- 12. The device of claim 7 wherein the drug is formulated in a diketopiperazine formulation.
- 13. The device of claim 7 wherein the dry powder formulation consists essentially of drug.
- 14. A method of administering a drug to the nasal region of a patient in need thereof, comprising nasally administering a dry powder form of a drug having an average particle size of between 10 and 20 microns, in a dosage formulation suitable for nasal administration.

NO. 2452 P. 15

U.S.S.N.: 09/766,362 Filed: January 19, 2001

RESPONSE TO OFFICE ACTION

- 15. The method of claim 14 wherein the drug is selected from the group consisting of antihistamine, vasoconstrictors, antiinflammatories and analgesics.
- 16. The method of claim 14 wherein the antihistamine is selected from the group consisting of chlorpheniramine and azelastine.
  - 17. The method of claim 14 wherein the drug is formulated in a polymeric carrier.
- 18. The method of claim 14 wherein the drug is formulated in a diketopiperazine formulation.
- 19. The method of claim 14 wherein the dry powder formulation consists essentially of drug.

541 F.2d 257 191 U.S.P.Q. 90 (Cite as: 541 F.2d 257)

> United States Court of Customs, and Patent Appeals.

## Application of John H. WERTHEIM et al.

### Patent Appeal No. 75-536.

Aug. 26, 1976.

Applicant for patent serial No. 96,285, with respect to a process for making freeze-dried instant coffee appealed from a decision of the Patent and Trademark Office Board of Appeals affirming the rejection of all claims in application. The appeal as to certain claims was withdrawn. The Court of Customs and Patent Appeals, Rich, J., held that certain claims were entitled to the benefit of the earlier filing date of Swiss application of applicants and were therefore improperly rejected while certain other claims were not entitled to such earlier filing date and were properly rejected and that certain other claims were properly rejected on ground of obviousness in view of prior art while other claims were improperly rejected on grounds obviousness.

Affirmed in part and reversed in part.

Baldwin, J., filed an opinion concurring in part and dissenting in part.

Miller, J., filed an opinion dissenting in part and concurring in part.

### West Headnotes

## [1] Patents \$\infty\$90(1) 291k90(1)

If patent applicants' parent and Swiss applications complied with specification statute, including description requirement, as to the subject matter of the interference claims, the claims were entitled to filing dates of parent application and Swiss application. 35 U.S.C.A. §§ 112, 119, 120.

# [2] Patents @= 101(5) 291k101(5)

Function of description requirement with respect to

application is to ensure that inventor had possession, as of filing date of application relied on, of specific subject matter later claimed by him; specification accomplishes this is not material. 35

# [3] Patents \$\infty\$101(5) 291k101(5)

U.S.C.A. § 112.

It is not necessary that application for patent describe claim limitations exactly but only so clearly that persons of ordinary skill in the art will recognize from disclosure that applicants invented processes including those limitations. 35 U.S.C.A. § 112.

### [4] Patents @ 101(5) 291k101(5)

In determining compliance with description requirement of statute with respect to limitations, the primary consideration is factual and depends on nature of invention and amount of knowledge imparted to those skilled in the art by the disclosure. 35 U.S.C.A. § 112.

### [5] Patents @ 113(7) 291k113(7)

On appeal from decision of patent and trademark office board of appeals affirming final rejection of claim, PTO had initial burden of presenting evidence of reasons that persons skilled in art would not have recognized in disclosure a description of invention defined by claims, and by pointing to fact that the claim read on embodiments outside scope of description the PTO satisfied its burden. U.S.C.A. § 112.

# [6] Patents @ 101(2) 291k101(2)

Where Swiss application on which applicant for continuation patent relied was filed prior to issuance of United States patent, for purpose of statute relating to specifications in patent application the United States patent disclosure was not evidence of what those skilled in art considered conventional at the time Swiss application was filed. 35 U.S.C.A. § 112.

541 F.2d 257 (Cite as: 541 F,2d 257)

Page 2

## [7] Patents © 90(1) 291k90(1)

Claims 1 and 4 of application relating to method for making freeze-dried instant coffee were not entitled to benefit of filing date of applicants' earlier Swiss application for patent since the claims in instant application relied on embodiments employing solids content outside range described in Swiss application.

# [8] Patents © 101(5) 291k101(5)

Where it is clear that the broad described range pertains to a different invention than narrower claimed range, then broader range does not describe narrower range for purpose of statute relating to specifications in application for patent. 35 U.S.C.A. § 112.

[9] Patents @ 66(1.24) 291k66(1.24)

# [9] Patents \$\infty\$90(1) 291k90(1)

Claims 2, 37 and 38 of patent application relating to process for making freeze-dried instant coffee claiming a solids content range within the described broad range of Swiss application were entitled to benefit of the filing date of the Swiss application which antedated the United States patent, which was not available as a prior art of its 1966 date, so that rejection of such claims was improper. 35 U.S.C.A. §§ 102(e), 103, 112.

# [10] Patents © 101(11) 291k101(11)

Claims 6-10, 12-15, 17, and 26 relating to application for patent for making freeze-dried instant coffee were improperly rejected on ground that limitation of particle size was not described in application as originally filed and was added to the application in violation of statute, since the originally filed specification clearly conveyed to those of ordinary skill in art that applicants invented process in which the particles were of particular size. 35 U.S.C.A. § 132.

# [11] Patents \$\infty\$ 51(1) 291k51(1)

Disclosure in prior art of any value within a claimed range is an anticipation of the claimed range. 35 U.S.C.A. § 103.

# [12] Patents \$\infty\$16.30 291k16.30

(Formerly 291k18)

With respect to patent application relating to process for making freeze-dried instant coffee, claims 6-14, 16, and 21-28 were properly rejected on ground of obviousness in view of the prior art while process claims 17-20 and 29 were improperly rejected on grounds of obviousness. 35 U.S.C.A. § 103.

# [13] Patents \$\iiin\$ 16.30 291k16.30 (Formerly 291k18)

Apparatus claims 30-35 of application for patent, with respect to a process for making freeze-dried instant coffee were properly rejected on grounds of obviousness in view of prior art. 35 U.S.C.A. § 103.

# [14] Patents \$\iiin\$ 16.30 291k16.30 (Formerly 291k18)

Patent claims 15 and 40-43 of application for patent relating to process for making freeze-dried instant coffee were properly rejected for obviousness in view of prior art.

# Patents 328(2) 291k328(2)

2,897,084, 2,974,497, 3,253,420, 3,482,990. Cited.

\*258 William H. Vogt, III, Watson, Leavenworth, Kelton & Taggart, New York City, attys. of record, for appellants; Paul E. O'Donnell, Jr., New York City, of counsel.

Joseph F. Nakamura, Washington, D. C., for the Commissioner of Patents; Gerald H. Bjorge, Washington, D. C., of counsel.

Before MARKEY, Chief Judge, and RICH, BALDWIN, LANE and MILLER, Judges.

541 F.2d 257 (Cite as: 541 F.2d 257, \*258)

RICH, Judge.

This appeal is from the decision of the Patent and Trademark Office (PTO) Board of Appeals affirming the final rejection of claims 1-43, all the claims in application serial No. 96,285, filed December 8, 1970, entitled "Drying Method." [FN1] The appeal on claims 3, 5, 36, and 39 has been withdrawn, and as to these claims it is, therefore, dismissed. As to the remaining claims, we affirm in part and reverse in part.

FN1. A continuation (or continuation-in-part, as the examiner has required it to be denominated) of application serial No. 537,679, filed March 28, 1966. Appellants claim the benefit of a Swiss application filed April 2, 1965. The title of the application on appeal is somewhat inaccurate, as the application contains claims to apparatus for drying and dried instant coffee products as well as to a drying method.

#### The Invention

Appellants' invention centers around a process for making freeze-dried instant coffee. Claims 1, 6, 30, and 40 are illustrative:

- 1. An improved process for minimizing loss of volatiles during freeze-drying of coffee extract which comprises obtaining coffee extract, concentrating said extract to a higher solids level of at least 35%, foaming said concentrated extract \*259 to a substantial overrun by injection of a gas into said extract at at least atmospheric pressure to thereby avoid evaporative cooling due to evaporation of water in said extract during said foaming, freezing said foam to below its eutectic point at at least atmospheric pressure while avoiding evaporative cooling, and freeze-drying said extract at below the eutectic temperature of said extract.
- 6. Process for preparing a powdered coffee extract, which comprises adding sufficient inert gas to a concentrated aqueous extract of roast coffee containing about 25% to 60% by weight of soluble coffee solids to provide a foam having a density between about 0.4 and 0.8 gm/cc, freezing the foamed extract to a solid mass, grinding the frozen foam to a particle size of at least 0.25 mm and freeze drying the ground frozen foam.
- 30. An apparatus for carrying out the process defined in claim 6 comprising, in combination, means for foaming, a closed chamber capable of

being maintained at a temperature which is substantially below the melting temperature of said frozen foam, and, disposed within said chamber, a movable endless belt, means for moving said belt at a low speed, a spreading device for distributing coffee extract foam on said belt and refrigerating means for cooling at least one surface of said belt with a liquid refrigerant.

40. A dry coffee powder comprising a freeze-dried particulated foamed extract of roast and ground coffee, the foam before freeze drying having a density between about 0.4 and 0.8 gm/cc.

The remaining claims are reproduced in the Appendix hereto. Appellants assert that their invention produces an instant coffee having a bulk density of 0.2-0.3 gm/cc, which corresponds to that of conventional spray-dried instant coffee. [FN2] They allege they discovered that this desired bulk density results from controlling the solids content of the concentrated extract prior to foaming and the density of the foam generated therefrom within the ranges of their freeze-drying process claims.

FN2. So that consumers may continue to use the same amount of freeze-dried instant coffee per cup as conventional instant coffee without change in the strength of the beverage that they are accustomed to.

Since the claims are somewhat elliptical in setting out the steps of appellants' process, we shall describe it further. An aqueous extract of coffee is prepared by percolating hot water through roasted and ground coffee beans. The extract is concentrated to have a solids content between 25% and 60% and is then charged with gas to produce a foam having a density between 0.4 and 0.8 gm/cc. The foam is frozen and ground into particles, preferably 0.25 to 2.0 mm in size, which are freezedried by conventional techniques.

### Prosecution History and Rejections

The claims which remain on appeal fall into two broad groups: The "interference" claims 1, 2, 4, 37, and 38; and the "non-interference" claims, 6-35 and 40-43.

As originally filed, the application contained claims 1-5 copied from Pfluger et al. U. S. Patent No. 3,482,990 (Pfluger patent), issued December 9, 1969, on an application filed February 10, 1969. A

541 F.2d 257 (Cite as: 541 F.2d 257, \*259)

Page 4

letter under Rule 205(a), 37 CFR 1.205(a), requesting an interference with the Pfluger patent accompanied the application. By amendment, appellants transferred claims 6-35 from their 1966 application to the instant application. Claims 36-39, added by amendment, are modified versions of the previously copied claims and were presented for the

purpose of providing a basis for phantom counts in an interference with the Pfluger patent under Rule 205(a) and Manual of Patent Examining Procedure s 1101.02. They depend from claim 2.

\*260 The patents relied on by the examiner are:

The Pfluger patent issued on a chain of four applications: serial No. 800,353, filed Feb. 10, 1969, which was a continuation of serial No. 520,347, filed Jan. 13, 1966 (Pfluger 1966), which was a continuation-in-part of serial No. 309,410, filed Sept. 17, 1963 (Pfluger 1963), which was a continuation-in-part of serial No. 98,007, filed Mar. 24, 1961. The Pfluger patent discloses a process for making freeze-dried instant coffee which has as its goal minimizing the loss from a foamed extract of volatile aromatics which contribute substantially to the natural flavor of coffee and other foods.

De George describes apparatus and methods for freezing liquid, unfoamed coffee extract prior to drying on continuous belts refrigerated by brine tanks contacting the bottom surfaces of the belts. The claims of De George are directed to processes for facilitating the removal of the frozen sheet of coffee extract from the belt before it is freeze dried.

The British patent discloses a rapid freeze-drying process in which the food product is frozen, milled into small particles which are spread from a hopper in single-particle layers onto plates, and freeze-dried in a vacuum chamber. More details of the disclosure are supplied infra.

Carpenter discloses the cooling of a refrigeration belt by spraying cold brine onto the underside of the belt.

The examiner made multiple rejections which were addressed by the board in eight categories, seven of which are before us for review. Category I covers the "interference" claims, which were rejected on the Pfluger patent, claims 1, 2, and 4 under 35 U.S.C. s 102 and claims 37 and 38 under s 103. The board agreed with the examiner's position that

these claims were not entitled to the benefit of appellants' 1965 Swiss priority date because they were not supported by appellants' parent and Swiss applications. The limitations held to be unsupported were "at least 35% (solids content)" in claim 1, "between 35% and 60% soluble solids" in claims 2 and 4, and "pressure of less than 500 microns" and "final product temperature of less than 1100 F." in claim 4. For that reason appellants were held to be junior to the Pfluger patent on the basis of Pfluger's 1966 filing date. In light of appellants' refusal to file a Rule 204(c) [FN3] affidavit showing a date of invention prior to Pfluger's 1966 filing date, the examiner and the board held the Pfluger patent to be prior art under s 102(e) against claims 1, 2, 4, 37, and 38 and rejected the claims on that basis.[FN4] The board refused to hold that the claims were supported in the parent and Swiss applications, "for interference purposes," under our decision in In re Waymouth, 486 F.2d 1058, 179 USPO 627 (Cust. & Pat.App.1973), mod. on reh., 489 F.2d 1297, 180 USPQ 453 (CCPA 1974). The board stated that appellants' failure to file a Rule 204(c) affidavit precluded any attempt to get into an interference and that Waymouth, which concerned the right to make a claim for interference purposes in the application on appeal, was therefore inapplicable to this case.

#### FN3. 37 CFR 1.204(c):

When the effective filing date of an applicant is more than 3 months subsequent to the effective filing date of the patentee, the applicant, before the interference will be declared, shall file two copies of affidavits or declarations by himself, if possible, and by one or more corroborating witnesses, supported by documentary evidence if available, each setting out a factual description of acts and circumstances performed or observed by the affiant, which collectively would prima facic

541 F.2d 257

(Cite as: 541 F.2d 257, \*260)

entitle him to an award of priority with respect to the effective filing date of the patent. This showing must be accompanied by an explanation of the basis on which he believes that the facts set forth would overcome the effective filing date of the patent.

FN4. The examiner and the board did not rely on Pfluger 1963 because the solids content and foam density ranges of the copied claims were not described in that application. In re Lund, 376 P.2d 982, 54 CCPA 1361, 153 USPQ 625 (1967).

\*261 Under Category II, the board affirmed the rejection of claims 6-10, 12-15, 17, and 26 under 35 U.S.C. s 132 for new matter. The board held that these claims, which were added to the instant application by amendment, were not supported in the original disclosure for lack of a description of the claimed size of the ground foam particles, i. e., "at least 0,25 mm."

The Category III rejection was reversed by the board.

In Category IV, claims 6-8, 11-20, and 40-43 were rejected under s 103 on the disclosure of Pfluger 1963 [FN5] carried forward to the Pfluger patent, in accordance with In re Lund, supra. The board found that the foam density range of 0.4-0.8 gm/cc claimed by appellants (and the 0.6-0.8 gm/cc range in claims 19 and 20) was suggested by Pfluger 1963's disclosure of 0.1-0.5 gm/cc foam density and that Pfluger 1963 teaches the use of foaming gases and concentrating the coffee extract prior to foaming. The board found that the final product densities claimed would be inherent "in view of the same foam overrun density disclosed by Pfluger" and that Pfluger's example I, which discloses breaking the frozen foam strands into 3/4 lengths (i. e., "at least 0.25 mm") before drying, would suggest the size of the ground foam particles claimed by appellants.

FN5. Peebles U. S. patent No. 2,897,084, issued July 28, 1959, was cited against claims 19 and 20 to show that agglomerating fine dried coffee particles into larger grounds was old in the art. Appellants have acknowledged this to be true, so it is not necessary to discuss Peebles further.

Category V added De George to the s 103 rejection

of claims 9, 10, 30, and 32-35. The board agreed with the examiner that the temperatures, foam thicknesses, and belt lengths and speeds covered by these claims are disclosed in De George, and that it would be obvious to use De George's moving belt apparatus in the Pfluger process.

In Category VI claims 21-23 and 26-29 were rejected under s 103 on Pfluger in view of the British patent, which was relied on for its teaching of the concentration of coffee extract by freezing to a solids content of 27 to 28%. Pfluger was applied to the claims under the rationale employed in Category IV.

Category VII was the rejection of claims 24 and 25 under s 103 on Pfluger, the British patent, and De George, which was relied on to show "the deposition of a coffee extract on a moving belt prior to grinding and freeze drying." The board otherwise relied on the reasoning in Categories V and VI.

Under Category VIII claim 31 was rejected on Pfluger and De George under s 103 for the reasons of Category V, with reliance on Carpenter to show refrigeration of the belt by spraying refrigerant onto the bottom of the belt instead of using De George's brine tanks.

# OPINION

The "Interference" Claims 1, 2, 4, 37, and 38

[1] The dispositive issue under this heading is whether appellants' parent and Swiss applications comply with 35 U.S.C. s 112, first paragraph, including the description requirement, as to the subject matter of these claims. If they do, these claims are entitled to the filing dates of the parent application under 35 U.S.C. s 120; In re Lukach, 442 F.2d 967, 58 CCPA 1233, 169 USPQ 795 (1971), and the Swiss application under 35 U.S.C. s 119, Kawai v. Metlesics, 480 F.2d 880, 887-88, 178 USPO 158, 164 (Cust. & Pat.App.1973). Since the PTO relies only on Pfluger 1966 to provide the effective U.S. filing date of the patent as a reference against these claims under ss 102(e) and 103, a right of foreign priority in appellants' Swiss application will antedate Pfluger 1966 and remove it as prior art against the claims.

The only defect asserted below in appellants' parent and Swiss application disclosures that covers all

APR. 10. 2002 5:46PM

541 F.2d 257

(Cite as: 541 F.2d 257, \*261)

these claims is that the applications do not contain written descriptions of the solids content limitations of the \*262 concentrated extract prior to foaming, i. e., "at least 35%" (claim 1) and "between 35% and 60%" (claims 2, 4, 37, and 38).[FN6]

> FN6. The solicitor belatedly asserts that the Swiss application is not "for the same invention" as the parent application, insofar as claims 1, 2, and 4 are concerned; he argues that the expression "same invention" in 35 U.S.C. s 119 should be given the meaning employed by us in the double patenting cases, e. g., In re Vogel, 422 F.2d 438, 57 CCPA 920, 164 USPQ 619 (1970). As we indicated in In re Ziegler, 347 F.2d 642, 52 CCPA 1473, 146 USPQ 76 (1965), the solicitor's reading is too narrow. All s 119 requires is that the foreign application describe and seek protection for "broadly the same invention" as described in the U.S. application claiming its benefit. 347 F.2d at 649, 52 CCPA at 1481, 146 USPQ at 82. The Swiss application has essentially the same disclosure as appellants' parent application and claims broadly the same invention.

Appellants' parent and Swiss applications contain virtually identical disclosures on this point. Both disclose that the coffee extract initially produced by percolation of water through ground roasted coffee is concentrated prior to foaming by suitable means "until a concentration of 25 to 60% solid matter is reached." Examples in each disclose specific embodiments having solids contents of 36% and 50%.

In our view, it is necessary to decide only whether the Swiss application complies with the description requirement of s 112 with respect to the questioned limitations. There is no question that the instant application supports claims 1, 2, and 4, which are original claims in that application. Appellants and the solicitor urge us to decide this case by determining whether the broad rule of In re Waymouth, supra, is still valid or must be disapproved. In the interest of judicial economy, we decline this entreaty since the issue of whether the Swiss application contains written descriptions of the disputed limitations of claims 1, 2, 4, 37, and 38, being addressed to strict compliance with s 112, first paragraph, is dispositive regardless of the validity of Waymouth in its own factual setting. sufficiency of the parent U.S. application need not be separately decided since appellants must have the benefit of their Swiss application date to antedate the

Page 6

Pfluger patent.

[2][3] The function of the description requirement is to ensure that the inventor had possession, as of the filing date of the application relied on, of the specific subject matter later claimed by him; how the specification accomplishes this is not material. In re Smith, 481 F.2d 910, 178 USPQ 620 (Cust. & Pat.App.1973), and cases cited therein. It is not necessary that the application describe the claim limitations exactly, In re Lukach, supra, but only so clearly that persons of ordinary skill in the art will recognize from the disclosure that appellants invented processes including those limitations. In re-Smythe, 480 F.2d 1376, 1382, 178 USPO 279, 284 (Cust. & Pat. App. 1973).

[4] The primary consideration is factual and depends on the nature of the invention and the amount of knowledge imparted to those skilled in the art by the disclosure. The factual nature of the inquiry was emphasized in In re Ruschig, 379 F.2d 990, 995-96, 54 CCPA 1551, 1558-59, 154 USPQ 118, 123 (1967), which involved the question whether a broad generic disclosure "described" the single chemical compound claimed:

But looking at the problem, as we must, from the standpoint of one with no foreknowledge of the specific compound, it is our considered opinion that the board was correct in saying:

Not having been specifically named or mentioned in any manner, one is left to selection from the myriads of possibilities encompassed by the broad disclosure, with no guide indicating or directing that this particular selection should be made rather than any of the many others which could also be made.

Appellants refer to 35 U.S.C. s 112 as the presumed basis for this rejection and emphasize language therein about enabling one skilled in the art to make the invention, arguing therefrom that one skilled in the art would be enabled by the specification to make chlorpropamide. We find the argument unpersuasive for two reasons. First, it presumes some motivation \*263 for wanting to make the compound in preference to others. While we have no doubt a person so motivated would be enabled by the specification to make it. this is beside the point for the question is not whether he would be so enabled but whether the specification discloses the compound to him, specifically, as something appellants actually

541 F.2d 257 (Cite as: 541 F.2d 257, \*263)

invented. We think it does not. Second, we doubt that the rejection is truly based on section 112, at least on the parts relied on by appellants. If based on section 112, it is on the requirement thereof that "The specification shall contain a written description of the invention \* \* \*." (Emphasis ours.) We have a specification which describes appellants' invention. The issue here is in no wise a question of its compliance with section 112, it is a question of fact: Is the compound of claim 13 described therein? Does the specification convey clearly to those skilled in the art, to whom it is addressed, in any way, the information that appellants invented that specific compound?

articulated rules are particularly inappropriate in this area. See, e. g., In re Smith, 458 F.2d 1389, 1394, 59 CCPA 1025, 1033, 173 USPQ 679, 683 (1972), in which this court felt obliged to overrule a supposed "rule" of In re Risse, 378 F.2d 948, 952-53, 54 CCPA 1495, 1500-01, 154 USPO 1, 5 (1967). Mere comparison of ranges is not enough, nor are mechanical rules a substitute for an analysis of each case on its facts to determine whether an application conveys to those skilled in the art the information that the applicant invented the subject matter of the claims. In other words, we must decide whether the invention appellants seek to protect by their claims is part of the invention that appellants have described as theirs in the That what appellants claim as specification. patentable to them is less than what they describe as their invention is not conclusive if their specification also reasonably describes that which they do claim. Inventions are constantly made which turn out not to be patentable, and applicants frequently discover during the course of prosecution that only a part of what they invented and originally claimed is patentable. As we said in a different context in In re-Saunders, 444 F.2d 599, 607, 58 CCPA 1316, 1327, 170 USPQ 213, 220 (1971):

To rule otherwise would let form triumph over substance, substantially eliminating the right of an applicant to retreat to an otherwise patentable species merely because he erroneously thought he was first with the genus when he filed. Cf. In re Ruff, 256 F.2d 590, 597, 45 CCPA 1037, 1049, (118 USPQ 340, 347) (1958). Since the patent law provides for the amendment during prosecution of claims, as well as the specification supporting claims, 35 USC 132, it is clear that the reference to "particularly pointing out and distinctly claiming

the subject matter which the applicant regards as his invention" in the second paragraph of 35 USC 112 does not prohibit the applicant from changing what he "regards as his invention" (i. e., the subject matter on which he seeks patent protection) during the pendency of his application. Cf. In re Brower, 433 F.2d 813, 817, 58 CCPA 724, (728), (167 USPQ 684, 687) (1970) (fact that claims in continuation application were directed to subject matter which appellants had not regarded as part of their invention when the parent application was filed held not to prevent the continuation application from receiving benefit of parent's date).

[5] Claims 1 and 4 present little difficulty. Claim 1 recites a solids content range of "at least 35%," which reads literally on embodiments employing solids contents outside the 25-60% range described in the Swiss application. As in cases involving the enablement requirement of s 112, e. g., In re Armbruster, 512 F.2d 676, 185 USPQ 152 (Cust. & Pat, App. 1975), we are of the opinion that the PTO has the initial burden of presenting evidence or reasons why persons skilled in the art would not recognize in the disclosure a description of the invention defined by the claims. By pointing to the fact that claim 1 reads on embodiments outside the scope of the description, the \*264 PTO has satisfied its burden. Appellants thus have the burden of showing that the upper limit of solids content described, i. e., 60%, is inherent in "at least 35%," as that limitation appears in claim 1. Appellants have adduced no evidence to carry this burden as to claim 1, and they argue only that since the Pfluger patent contains claim 1 supported by Pfluger's disclosure with a stated upper limit of 60%, like Swiss disclosure, refusal to grant appellants' appellants claim 1 amounts to an illegal reexamination of claim 1 in Pfluger. However, as we have often repeated, as recently as In re Giolito, 530 F.2d 397, 188 USPQ 645 (Cust. & Pat.App.1976), it is immaterial in ex parte prosecution whether the same or similar claims have been allowed to others.

[6] Claim 4 contains the additional limitations, relating to the "final product temperature" and the pressure at which the frozen foam is vacuum freezedried, of "less than 1100 F." and "less than 500 microns." "Final product temperature," it appears, refers to the temperature at which so-called bound

water is driven off from the product by heating after. the vacuum drying phase has ended. We find no description of final product temperature in appellants' Swiss application. It is not disputed that appellants do not expressly disclose final product temperatures or this secondary drying step. They again appeal, however, to the Pfluger patent disclosure and to an amendment entered in the application on appeal (not objected to as new matter by the examiner) to show that final product temperatures are conventional in the art and need not be expressly disclosed. The amendment is clearly irrelevant since claim 4, an originally filed claim, is its own written description in the appealed application. In re Gardner, 475 F.2d 1389, 177 USPQ 396, rehearing denied, 480 F.2d 879, 178 USPQ 149 (Cust. & Pat.App.1973). The issue is whether the Swiss application describes the claimed final product temperature, not whether the instant application does so. The Pfluger patent disclosure is also unavailable to appellants. The Swiss application was filed before Pfluger issued, which means that for the purposes of s 112 the Pfluger disclosure is not evidence of what those skilled in the art considered conventional at the time the Swiss application was filed. In re Glass, 492 F.2d 1228, 181 USPQ 31 (Cust. & Pat. App. 1974). [FN7]

PN7. That the final product temperature limitation is not material, as appellants argue, does not matter when the limitation is copied. Immateriality excuses only failure to copy a limitation of a patent claim. See Brailsford v. Lavet, 318 F.2d 942, 50 CCPA 1367, 138 USPQ 28 (1963); 37 CFR 1.205(a).

- [7] Claims 1 and 4, therefore, are not entitled to the benefit of the filing date of appellants' Swiss application.
- [8] Claims 2, 37, and 38, which claim a solids content range of "between 35% and 60%," present a different question. They clearly claim a range within the described broad range of 25% to 60%, solids; the question is whether, on the facts, the PTO has presented sufficient reason to doubt that the broader described range also describes the somewhat narrower claimed range. We note that there is no evidence, and the PTO does not contend otherwise, that there is in fact any distinction, in terms of the operability of appellants' process or of the achieving of any desired result, between the claimed lower limit of solids content and that disclosed in the Swiss

application. We see an important practical distinction between broad generic chemical compound inventions, for example, as in In re Ruschig, supra, in which each compound within the genus is a separate embodiment of the invention. and inventions like that at bar, in which the range of solids content is but one of several process parameters. What those skilled in the art would expect from using 34% solids content in the concentrated extract prior to foaming instead of 35% is a different matter from what those skilled in the art would expect from the next adjacent homolog of a compound whose properties are disclosed in the specification. We wish to make it clear that we are not creating a rule applicable to all description requirement cases involving \*265 ranges. Where it is clear, for instance, that the broad described range pertains to a different invention than the narrower (and subsumed) claimed range, then the broader range does not describe the narrower range. In re-Baird, 348 F.2d 974, 52 CCPA 1747, 146 USPO 579 (1965); In re Draeger, 150 F.2d 572, 32 CCPA 1217, 66 USPQ 247 (1945).

In the context of this invention, in light of the description of the invention as employing solids contents within the range of 25-60% along with specific embodiments of 36% and 50%, we are of the opinion that, as a factual matter, persons skilled in the art would consider processes employing a 35-60% solids content range to be part of appellants' invention and would be led by the Swiss disclosure so to conclude. Cf. In re Ruschig, supra. The PTO has done nothing more than to argue lack of literal support, which is not enough. If lack of literal support alone were enough to support a rejection under s 112, then the statement of In re Lukach, supra, 442 F.2d at 969, 58 CCPA at 1235, 169 USPQ at 796, that "the invention claimed does not have to be described in ipsis verbis in order to satisfy the description requirement of s 112," is empty verbiage. The burden of showing that the claimed invention is not described in the specification rests on the PTO in the first instance, and it is up to the PTO to give reasons why a description not in ipsis verbis is insufficient.

[9] We conclude, therefore, that claims 2, 37, and 38 are entitled to the benefit of the filing date of appellants' Swiss application.

Since the Pfluger patent is not available as prior art

APR. 10. 2002

541 F.2d 257

(Cite as: 541 F.2d 257, \*265)

Page 9

as of its 1966 date under ss 102(e) and 103 against claims 2, 37, and 38, the rejection of those claims is The rejection of claims 1 and 4 is reversed. affirmed. Appellants filed no affidavit under Rule 204(c) showing a date of invention for claims 1 and 4 prior to Pfluger's 1966 filing date, In re Gemassmer, 319 F.2d 539, 51 CCPA 726, 138 USPQ 229 (1963), and have not antedated Pfluger as to those claims under 35 U.S.C. ss 119 and 120.

### The New Matter Rejection

[10] The issue to be decided here is whether the limitation appearing in claim 6, carried forward into the other claims affected by this rejection, that the frozen foam be ground "to a particle size of at least 0.25 mm" before it is dried, was added to the instant application in violation of 35 U.S.C. s 132. This new matter rejection rests on a finding by the PTO that the application as filed did not describe this limitation. Thus, the converse of what we said in In re Bowen, 492 F.2d 859, 864, 181 USPQ 48, 52 (Cust. & Pat.App.1974), is true in this case, namely, that this new matter rejection is tantamount to a rejection of the claims on the description requirement of 35 U.S.C. s 112, first paragraph. The solicitor agrees with this.

We conclude that the originally filed specification clearly conveys to those of ordinary skill in the art that appellants invented processes in which the frozen foam is ground to a particle size of "at least .025 mm," and not, as the PTO asserts, only processes in which the particle sizes are no larger than 2 mm. See In re Smythe, supra.

The specification states, inter alia (emphasis ours): At the end of the (cooling) belt the extract is removed as a continuous rigid sheet which may then be broken up into fragments suitable for grinding. These fragments may, for example, be ground to a particle size which is preferably within the range 0.25 to 2.0 mm.

In a modification of the process, the frozen extract may be freeze-dried in the form of plates or lumps which are subsequently ground to the desired particle size.

The examples speak of drying frozen ground particles of sizes between 0.1 and 2 mm. While the

specification indicates that the 0.25 to 2.0 mm range is preferred, we think it clearly indicates that, as an alternative embodiment of appellants' invention. \*266 the foam may be dried in lumps or plates of undisclosed size, which are reduced to the obviously smaller preferred particle size by grinding only after being dried. The solicitor argues that the claimed "range" has no upper limit, wherefore it is not disclosed. The clear implication of this disclosed modification is that appellants' specification does describe as their invention processes in which particle size is "at least 0.25 mm," without upper limit, as delineated by the rejected claims. The rejection of claims 6-10, 12-15, 17, and 26 under 35 U.S.C. s 132 is reversed.

### The "Non-Interference" Claims 6-35 and 40-43

In the Examiner's Answer, appellants were granted the benefit of the filing date of their Swiss application for claims 16-25, 27-35, and 40-43. The examiner stated: "Claims 6-15 and 26, except for new matter, would otherwise be supported in the Swiss application." Our reversal of the new matter rejection eliminates the basis for the examiner's refusal to give claims 6-15 and 26 the benefit of appellants' Swiss filing date. Appellants' parent and Swiss applications contain the same disclosures concerning particle size as does the application on appeal, and we shall treat all the claims under this heading as entitled to the right of foreign priority claimed by appellants.

Our analysis of these claims will be broken down by the type of claim involved, i. e., process. apparatus, and product, and not as the board addressed them. In each discussion we will apply as prior art under s 102(e) only those portions of the Pfluger patent disclosure that were carried forward from the Pfluger 1963 application (Pfluger 1963) through the two subsequent applications into the patent, as did the board. In re Lund, supra.

### A. Process Claims 6-14 and 16-29

There are four independent process claims: claim 6. from which claims 7-14, 16, and 17 depend; claim 18; claim 19, from which claim 20 depends; and claim 21, from which claims 22-29 depend.

Pfluger 1963 contains the following disclosure, which, in substance, is carried forward into the 541 F.2d 257 (Cite as: 541 F.2d 257, \*266) Page 10

#### patent:

This invention is founded on the discovery that an aqueous aromatic liquid containing solids in suspension and solution may be dried without undergoing loss of aromatic volatiles by a process which comprises foaming the aqueous liquid to a substantial overrun while avoiding evaporation of said aqueous liquid, freezing said foam to below its eutectic point while avoiding evaporation of the aqueous liquid, subliming said aqueous liquid from the frozen foam to reduce the moisture of the foam to at least 10-20%, and further drying the foam to a stable moisture content.

\* \* \*

In many applications such foaming can be considerably increased by concentrating the solution or suspension to a relatively high solids content prior to incorporation of air or other gas such as nitrogen therein by first whipping and then freezing the foam, preferably by conductive freezing. During the foaming step, it is essential in order to prevent loss of volatiles to avoid any evaporative cooling of the material, i. e., evaporation of water during the foaming step. Also, during the freezing step evaporative cooling should be avoided. Other ways for creating a frozen foam without undergoing evaporative cooling involve the overt introduction to a solution or suspension of dry ice, i. e., solid carbon dioxide in a suitably ground or particulate form. whereby carbon dioxide gas is liberated upon subliming of the "dry ice" to cause foaming of the solution or suspension to occur. refrigerated air or nitrogen can be introduced to the solution or suspension to cause freezing thereof incident to foaming the material. The foam preferably has a high overrun whereby the density of the solution or suspension is changed from above 1.0 gm./cc. to between 0.1-0.5 gms/cc.

Example I, the sole disclosed embodiment in which the foam density is given, shows \*267 foaming the extract to a density of 0.22 gm/cc.

Claims 19 and 20 recite a foam density of "between about 0.6 and about 0.8 gm/cc," outside the range disclosed by Pfluger 1963. The examiner's position was that Pfluger's disclosure of 0.5 gm/cc as an upper density limit suggests "about 0.6 gm/cc" as the lower limit in the processes of claims 19 and 20 "in the absence of a critical difference between

them." We see no such suggestion. By preferring a high foam overrun, i. e., lower rather than higher foam densities, Pfluger 1963 teaches away from employing higher foam densities than its disclosed upper limit of 0.5 gm/cc. Appellants' "about 0.6 gm/cc" lower limit is sufficiently precise to describe foam densities above 0.5 gm/cc and thus outside the range of foam densities that persons of ordinary skill in the art would have been motivated to use by Pfluger 1963's disclosure of a preference for high overnun foams no denser than 0.5 gm/cc. The examiner's comment about the lack of a showing of a critical difference is based on his failure to appreciate that Pfluger 1963 teaches away from increasing foam density. The rejection of claims 19 and 20 under s 103 is reversed.

[11][12] Claims 6-14, 16, 17, and 21-29 recite foam density ranges of " between about 0.4 and 0.8 gm/cc" and solids contents in the range of "about 25% to 60%." Claims 6-10, 12-14, 17, and 26 recite particle sizes of "at least 0.25 mm," claims 16 and 27 say "about 0.25 to 2 mm," claims 11 and 28 recite particle sizes "approximately equal to that of roast and ground coffee," and claims 21-25 do not mention particle size. Pfluger 1963's disclosed foam density range of 0.1-0.5 gm/cc covers values within the scope of all the above-listed claims; the solids contents disclosed in Pfluger 1963 Examples I (27%) and V (30%) are within the claimed ranges of 25-60%. Pfluger 1963 clearly teaches a process for making instant coffee comprising the steps of preparing and concentrating aqueous coffee extract, foaming the extract then freezing the foam, and drying the frozen foam, in that order. Pfluger 1963 teaches fragmenting the frozen foam into 3/4-inch pieces before drying; 3/4 inch is, of course, "at least 0.25 mm." Of course, the disclosure in the prior art of any value within a claimed range is an anticipation of the claimed range. We appreciate the arguments made in In re Malagari, 499 F.2d 1297, 182 USPQ 549 (Cust. & Pat.App.1974), and the discussion In re Orfeo, 440 F.2d 439, 58 CCPA 1123, 169 USPQ 487 (1971), to the effect that ranges which overlap or lie inside ranges disclosed by the prior art may be patentable if the applicant can show criticality in the claimed range by evidence of unexpected results. The rejections here are under s 103, not s 102, which requires us to consider appellants' argument that their invention and Pfluger's disclosure are directed to different purposes and that persons of ordinary skill in the art

541 F.2d 257

(Cite as: 541 F.2d 257, \*267)

Page 11

would not look to Pfluger 1963 for a solution to the problem addressed by appellants. See In re Orfeo, supra.

Appellants' contentions were thus stated in their main brief:

The Board erred at the threshold in failing to appreciate that neither the Pfluger patent nor the 1963 Pfluger application gives any inkling or hint of the inventive concept underlying the rejected claims. \* \* \* The Pfluger disclosures make no mention of product bulk density and contain no suggestion of altering or regulating that density in any manner. Neither does the reference suggest appellants' step of grinding the foam before freeze drying.

\* \* \*

One of ordinary skill in the art reading the 1963 Pfluger disclosure would have no inkling of the problem addressed and solved by appellants; and one looking for ways to meet that problem would have no occasion to consider Pfluger or his expedients.

Without an antecedent basis for it in their application, appellants may not use this rationale to show unobviousness. In re Davies, 475 F.2d 667, 177 USPQ 381 (Cust. & Pat.App.1973). While appellants do disclose what the bulk density of their product \*268 "usually" is, we find no suggestion in appellants' application that their invention is addressed to the regulation of the bulk density of the product, and the claims make no express reference to such regulation. The only references in appellants' disclosure to this alleged problem and its solution which are apparent to us are (emphasis ours):

After freeze-drying, the coffee extract is obtained in the form of a powder the density of which is usually 0.2 to 0.3 gm/cc.

\* \* \*

Drying of the concentrated extract should desirably be carried out under controlled conditions such that the finished product possesses an appropriate density and colour. \* \* \*

\* \* \* The conditions of freezing, notably belt speed, freezing temperature, thickness of foam layer as well as the density of the foam, are factors which have an important influence on the colour of the finished product and should therefore be carefully controlled.

The inadequacy of this disclosure is evident. There is no mention of regulating the final product density or of controlling solids content. We therefore see no basis for depreciating Pfluger as evidence of the scope and content of the prior art, as well as of the level of ordinary skill in this art, as appellants would have us do. Nor is there any factual basis for concluding that the ranges claimed by appellants are critical in themselves to their alleged inventive contribution.

We find no error in the rejection under s 103 of claims 6-14, 16, and 21-28, which recite no final product density. The only difference between claims 6, 12-14, and 16 and the Pfluger 1963 disclosure upon which appellants rely to show the unobviousness of the subject matter of the claims (and which does not relate to solids content or foam density) is the step of "grinding the frozen foam to a particle size of at least 0.25 mm" prior to freezedrying.[FN8] Pfluger 1963, appellants assert, "fragments" the frozen foam prior to drying and "grinds" the foam only after it has been dried. As indicated above, the size of the fragments of frozen foam disclosed by Pfluger 1963 is "at least 0.25 mm." We do not think this difference shows the subject matter to be unobvious. Pfluger 1963 implies that the sizes of foam particles before and after drying are comparable; it would have been obvious to reduce the size of the foam particles by suitable mechanical means, whether it be called fragmenting or grinding, to the desired end product size before rather than after drying. Claim 11 differs only in its recitation of final product particle size, which Pfluger 1963 shows is an obvious matter of choice for those of ordinary skill in the art, who know how large ground roasted coffee bean particles are. The commercial motivation for making the particles this size is obvious. Appellants have not argued the patentability separately from claim 6 of claims 9 and 10, which add temperature and foam thickness limitations suggested by Pfluger and De George, as discussed infra in considering claims 24 and 25.

FN8. Appellants do not deny that the features added in claims 7, 12, 13, and 14 are taught in the art, and the record shows them to be known in the prior art.

Claim 8 likewise recites no final product density,

(Cite as: 541 F.2d 257, \*268)

but it requires that the freezing of the foam take place over a period of 7 to 25 minutes, which, appellants' application indicates, produces instant coffee "having a pleasant dark colour." Pfluger 1963 discloses freezing in liquid nitrogen or liquid air, which would be instantaneous, or rapid freezing on a belt, and states further. "The foam may be frozen at a high or a more gradual rate without any apparent difference in the utility thereof insofar as freeze drying is concerned \* \* \*." (Emphasis ours.) Appellants have not shown that only their claimed freezing time produces coffee with a pleasant dark color. Thus, they have not overcome the prima facie case of obviousness made our by Pfluger 1963.

In light of appellants' concession in the amendment in which they added claims 37-39 that freeze concentration was known in the art, the rejection of claims 21-23, and \*269 26-28 under Category VI, supra, becomes little more than a rejection on Pfluger 1963 alone. With the exception of freeze concentration, which is disclosed by the British patent, every element of claim 21 is disclosed by Pfluger 1963, as indicated supra. Appellants advance no arguments for the patentability of claim 21 different from those we have already rejected for claim 6. Claim 22 adds only a recitation of the inert gases used in the foaming step, which were known in the prior art. Claims 26-28 recite the particle sizes of claims 6, 16, and 11, respectively; these particle sizes are not sufficient to show unobviousness for the reasons given supra. Claim 23, which was also rejected under Category VI. recites the freezing time of claim 8. unpatentable for the same reasons given for claim 8, supra.

Claims 24 and 25, to which Pfluger 1963, De George, and the British patent were applied under s 103, call for the temperature and foam limitations already discussed under claims 9 and 10, supra. Temperature and foam thicknesses within the claimed ranges are disclosed by Pfluger 1963 in Example VI (freezing foam at -300 F. on a belt and subsequently loading foam onto trays to a 1-inch (approx. 25 mm) depth for vacuum drying). Appellants do not allege that the ranges of claims 24 and 25 are critical.

Claims 17, 18, and 29, on the other hand, recite the bulk density of the final product made by each process in positive terms. The board dismissed

these final product density limitations as being merely recitations of the inherent result of observing the foam density and solids content ranges set forth in these claims. Although we found above that appellants' specification as filed does not disclose regulating product density by controlling the foam density and solids content in the process and that claims which failed to recite controlled product density could not rely on this feature to distinguish over the prior art under s 103, these claims do require such regulation or control, by implication through their express recitation of the density of the final product to be obtained from the processes they delimit. That persons skilled in the art may not know how to ensure the claimed final product densities from the specification is pertinent only to a rejection on the enablement requirement of s 112, first paragraph, which is not before us. The only question here is whether the subject matter of claims 17, 18, and 29, the scope of which is unquestionably clear, is obvious under s 103.

Pfluger 1963 discloses no final product densities and contains no teaching on how to achieve any particular final product density from practicing its process. The inherency of final product density adverted to by the board can be gleaned only from appellants' disclosure, if anywhere, which may not be used against them as prior art absent some admission that matter disclosed in the specification is in the prior art. In re Kuehl, 475 F.2d 658, 177 USPQ 250 (Cust, & Pat. App. 1973); cf. In re Nomiya, 509 F.2d 566, 184 USPQ 607 (Cust. & Pat. App. 1975). In the absence of disclosure of final product densities or how to achieve any desired density in the prior art applied by the PTO to claims 17, 18 and 29, we cannot say that the subject matter of these claims would have been obvious to persons of ordinary skill in the art.

The rejection of process claims 6-14, 16, and 21-28 is affirmed, the rejection of claims 17-20, and 29 is reversed.

### B. Apparatus Claims 30-35

[13] The preamble of independent claim 30, carried forward into claims 31-35, recites that the apparatus is "for carrying out the process in claim 6." Appellants contend that this preamble gives "life and meaning" to the claims, serving to define the interrelationship of the mechanical elements recited 541 F.2d 257

Page 13

(Cite as: 541 F.2d 257, \*269)

in the body of the claims. This argument appears to be based on Kropa v. Robie, 187 F.2d 150, 38 CCPA 858, 88 USPQ 478 (1951), the classic case in this court on the construction of claim preambles. In Kropa the court surveyed prior cases and \*270 said, 187 F.2d at 152, 38 CCPA at 861, 88 USPQ at 480-81:

(I)r appears that the preamble has been denied the effect of a limitation where the claim or count was drawn to a structure and the portion of the claim following the preamble was a self-contained description of the structure not depending for completeness upon the introductory clause \* \* \* . In those cases, the claim or count apart from the introductory clause completely defined the subject matter, and the preamble merely stated a purpose or intended use of that subject matter.

While we do not subscribe to the broad proposition that process limitations can never serve to distinguish the subject matter of apparatus claims from the prior art, we fail to see how the general process parameters of claim 6 require an arrangement of the apparatus means recited in claims 30-35 more specific than that set forth in the body of each claim. In no claim is the preamble relied on to provide an antecedent basis for terms in the body. See In re Higbee, 527 F.2d 1405, 188 USPO 488 (Cust. & Pat.App, 1976). The context of each invention is clear without reference to claim 6. unlike the situation in Kropa, supra, in which the preamble "An abrasive article" was the only portion of the claim defining the relationship of the components recited in the body of the claim; the court said, "The term calls forth a distinct relationship between the proportions of grain and resin comprising the article." 187 F.2d at 152, 38 CCPA at 862, 88 USPQ at 481.

Appellants do not argue the patentability of claims 32-35 separately from claim 30 and concede that Carpenter discloses the feature added in claim 31. We find that the teachings of Pfluger and De George (and Carpenter on claim 31) show that the subject matter of claims 30-35 would have been obvious to persons of ordinary skill in the art. references are to be viewed for what they disclose in their entireties and not merely for their inventive contributions to the art. In re Ogiue, 517 F.2d 1382, 1387, 186 USPQ 227, 232 (Cust. & Pat.App.1975).

Pfluger 1963, in a portion carried forward to the patent, discloses the following:

Advantageously, in following the teachings of the present process either in a vacuum freeze drying application or in an atmospheric freeze drying application, the frozen foamy mass may be arranged for either batch or continuous processing in any one of a variety of conventional plant handling applications. Thus, the foamy mass can be readily transferred from one food handling station to another, deposited in trays or continuous belts, superposed on one another or otherwise conventionally located in the vicinity of the freeze drying influences. In the case of a typical freeze drying operation the foams may be frozen and deposited onto trays stacked one above the other on a suitable heat transfer surface in a vacuum chamber. In the case of an atmospheric freeze drying application the foams can be stacked one upon the other upon a foraminous drying member permitting the circulation of the drying medium, e. g. dry air, helium or nitrogen. Throughout all of such freeze drying applications it is imperative that the temperature of the foamy mass be maintained below the cutectic point of the material while drying to assure that the foam stays in a substantially solid or frozen state as distinguished from a melted or semi-liquid state, dehydration of the mass being achieved by a process of sublimation as distinguished from one of evaporation. Such conditions should be followed at least until the moisture content of the foamy mass has been substantially reduced to a point where it has lost at least a majority of its moisture and preferably is superficially dry to the touch, i. e. in the neighborhood of 10-20% moisture by weight.

Example VI of Pfluger 1963, which is carried forward as Example III of the Pfluger patent, shows heat controlling the vacuum chamber to assure a product temperature below -100 F. (De George teaches that the melting point of a 28% solids content extract is about 270 F., whereas the eutectic temperature is constant regardless of concentration \*271 at about -13.50 F.) De George discloses the use of endless belts, low speeds, and refrigerating means, and appellants, while arguing that De George treats the handling of solid slabs of frozen extract on refrigeration belts and not frozen foamed extracts, do not and cannot deny that De George discloses apparatus that persons of ordinary skill in

541 F.2d 257 (Cite as: 541 F.2d 257, \*271)

the art would have deemed suitable for handling foams in the manner shown by Pfluger. Appellants also contend that neither reference discloses the "spreading device" recited in the claims, Pfluger 1963 showing only the application of 1/8 diameter ribbons of foam through a nozzle to stationary freeze drying trays. The reference in the portion of Pfluger 1963 quoted supra to the deposition of the foam on the belts is ample suggestion, in our opinion, that some means must be employed to apply the foamy mass to the continuous belts. The term "spreading device" is not defined in any special way by appellants and is broad enough to be the means for applying the foam to the belt suggested by Pfluger. The rejection of claims 30-35 is affirmed.

### C. Product Claims 15-and 40-43

[14] These claims are cast in product-by-process form. Although appellants argue, successfully we have found, that the Pfluger 1963 disclosure does not suggest the control of bulk density afforded by appellants' process, the patentability of the products defined by the claims, rather than the processes for making them, is what we must gauge in light of the prior art. See In re Bridgeford, 357 F.2d 679, 53 CCPA 1182, 149 USPQ 55 (1966). Each of these claims defines a freeze-dried instant coffee product made by processes which, appellants have contended with respect to their process claims, produce, by virtue of the foam density and solids content ranges taught by appellants, products having a bulk density comparable to spray-dried instant coffee, i. e., gm/cc as indicated in appellants' specification. The solids content and foam density ranges disclosed by Pfluger 1963 overlap those of appellants, and, it appears, the Pfluger process using solids contents and foam densities overlapping those of appellants will produce instant coffee which is indistinguishable from appellants' products. There is no evidence showing that Pfluger's product prepared, for example, using an extract of 30% solids content foamed to a density of 0.5 gm/cc differs from appellants' claimed products in any way, certainly not in any unobvious way. See In re Avery, 518 F.2d 1228, 1233-34, 186 USPO 161. 165-66 (Cust. & Pat.App. 1975). That some of the products covered by appellants' claims may not be disclosed or suggested by Pfluger 1963 is not relevant to patentability, since the claims embrace other subject matter completely disclosed by Pfluger 1963, complete disclosure in the prior art being the

Page 14

epitome of obviousness. In re Pearson, 494 F.2d 1399, 181 USPQ 641 (Cust. & Pat.App.1974). The rejection of these product claims under s 103 on Pfluger [FN9] is affirmed.

FN9. Appellants argue in their reply brief that claims 40-43 "were never the subject of an accurate or proper rejection," because the examiner and the board incorrectly grouped them with other claims. As we have indicated, the rejection of claims 40-43 on Pfluger under s 103 was "proper"; appellants do not contend that they could not understand the basis for the rejection because of failure of the PTO to give clear reasons for its action under 35 U.S.C. s 132, and we find the explanations given by the examiner and board with respect to claims 40-43 to have been legally ample under s 132. Cf. In re Gustafson, 331 F.2d 905, 51 CCPA 1358, 141 USPQ 585 (1964).

### Conclusion

The appeal is dismissed as to withdrawn claims 3, 5, 36, and 39. The decision of the board is affirmed as to claims 1, 4, 6-16, 21-28, 30-35 and 40-43, and is reversed as to claims 2, 17-20, 29, 37, and 38.

### MODIFIED APPENDIX

- 2. The process of claim 1 wherein the extract is concentrated to between 35% and 60% soluble solids prior to the foaming step.
- \*272 3. The process of claim 2 wherein the concentrated extract is foamed to an overrun density of between 0.1 to 0.7 gm/cc.
- 4. The process of claim 2 wherein the frozen foam is vacuum freeze-dried at a pressure of less than 500 microns and a final product temperature of less than 1100 F.
- 5. The process of claim 3 wherein the frozen foam is vacuum freeze-dried at a pressure of less than 500 microns and a final product temperature of less than 1100 C.
- 7. A process according to claim 6 in which said inert gas is at least one of the following gases, namely carbon dioxide, nitrous oxide and nitrogen.
- 8. A process according to claim 6 in which the foam is frozen during 7 to 25 minutes.

541 F.2d 257 (Cite as: 541 F.2d 257, \*272)

- 9. A process according to claim 6 in which the foam is frozen on a moving belt which is cooled to a temperature between -12 and -700 C.
- 10. A process according to claim 6 wherein the foam is spread on the belt at a layer thickness of 10 to 40 mm.
- 11. A process according to claim 6 in which the frozen foam is ground, before freeze-drying, to a particle size approximately equal to that of roast and ground coffee.
- 12. A process according to claim 6 in which an aromatic condensate obtained by stripping roast and ground coffee is added to said concentrated extract before it is transformed into a foam.
- 13. A process according to claim 6 in which, after freeze-drying, the powdered coffee extract is aromatised by incorporation therein of 0.1 to 0.5% by weight of an aromatic condensate obtained by stripping of roast and ground coffee.
- 14. A process according to claim 13 in which said condensate is incorporated in said powdered extract in admixture with an oily carrier.
- 15. The coffee extract obtained by the process defined in claim 6.
- 16. Process according to claim 6 in which the frozen foam is ground to a particle size of about 0.25 to 2.0 mm.
- 17. Process according to claim 6 in which the freeze dried extract has a density of about 0.2 to 0.3 gm/cc.
- 18. Process for preparing a soluble coffee extract, which comprises adding inert gas to a concentrated aqueous extract of roast coffee having a solids content of about 25% to about 60% to provide a foam, freezing the foam to a solid mass, reducing the frozen foam to particles having a size of about 0.25 to 2.0 mm and freeze drying the frozen particles, the amount of inert gas added to the aqueous extract being sufficient to provide a freeze dried extract having a density between about 0.2 and 0.3 gm/cc.
- 19. Process for preparing a powdered coffee extract

which comprises adding sufficient inert gas to a concentrated aqueous extract of roast coffee to provide a foam having a density between about 0.6 and about 0.8 gm/cc, freezing the foamed extract to a solid mass, grinding the frozen foam to an average particle size of 0.1 to 0.5 mm, freeze drying the ground particles to provide a finely powdered coffee extract, and agglomerating the finely powdered coffee extract.

- 20. Process according to claim 19, in which the powdered extract is agglomerated to provide an agglomerate having a density of about 0.2 to 0.3 gm/cc.
- 21. Process for preparing a powdered coffee extract which comprises increasing the soluble coffee solids content of an aqueous extract of roast ground coffee to about 25%-60% by freeze concentration, separating the concentrated extract from ice crystals, adding an inert gas to the concentrated aqueous extract to provide a foam having a density between about 0.4 and 0.8 gm/cc, freezing the foam to a solid mass and freeze drying the frozen foam.
- 22. Process according to claim 21 in which the inert gas is selected from the group consisting of carbon dioxide, nitrous oxide and nitrogen.
- \*273 23. Process according to claim 21 in which the foam is frozen during 7 to 25 minutes.
- 24. Process according to claim 21 in which the foam is frozen on a moving belt which is cooled to a temperature between -12 and -70DEGREES C.
- 25. Process according to claim 24 wherein the foam is spread on the belt at a layer thickness of 10 to 40 mm.
- 26. Process according to claim 21 in which the frozen foam is ground before freeze drying to a particle size of at least 0.25 mm.
- 27. Process according to claim 26 in which the frozen foam is ground to a particle size of about 0.25 to 2mm.
- 28. Process according to claim 21 in which the frozen foam is ground before freeze drying to a particle size approximately equal to that of roast and ground coffee.

541 F.2d 257 (Cite as: 541 F.2d 257, \*273)

- 29. Process according to claim 21 in which the freeze dried extract has a density of about 0.2-0.3 gm/cc.
- 31. An apparatus according to claim 30 in which the means for cooling the belt includes a plurality of sprinklers disposed to spray the refrigerant onto the underside of the belt.
- 32. An apparatus according to claim 30 in which the belt comprises two sections each provided with separate cooling means, the first of said sections being cooled to a temperature of -12 to -29DEGREES C and the second section to -40 to -70DEGREES C.
- 33. An apparatus according to claim 30 also comprising means for fragmenting and milling the frozen foam.
- 34. An apparatus according to claim 30 in which the length of said belt is 15 to 25 metres and the driving means is adapted to move said belt at a linear speed of about 0.5 to 1.5 m/min.
- 35. An apparatus according to claim 30 in which said chamber is adapted to be maintained at a temperature of -25 to -450 C.
- 36. The process of claim 2 wherein the concentrated extract is foamed to an overrun density of between about 0.1 to 0.8 gm/cc.
- 37. The process of claim 2 wherein the concentrated (506) extract is foamed to an overrun density of between 0.4 to 0.8 gm/cc.
- 38. The process of claim 2 wherein the frozen foam is vacuum freeze-dried at a pressure of about 150 to 175 microns.
- 39. The process of claim 3 wherein the frozen foam is vacuum freeze-dried at a pressure of about 150 to 175 inicrons.
- 41. A coffee powder according to claim 40 wherein the extract before freeze drying contains about 25% to 60% by weight of soluble coffee solids.
- 42. A dry coffee powder having a density of about 0.2 to 0.3 gm/cc and comprising a freeze dried particulated foamed extract of roass and ground

coffee, said extract containing before freeze drying up to about 60% by weight of soluble coffee solids.

43. A coffee powder according to claim 42 containing about 0.1% to 0.5% by weight of aromatic condensate obtained by stripping roast and ground coffee.

BALDWIN, Judge (concurring in part and dissenting in part).

I agree with Judge Miller's treatment of claims 17-20 and 29. Otherwise, I join the majority opinion.

MILLER, Judge (dissenting in part and concurring in part).

I dissent on claim 1. The error of the majority in affirming the rejection stems from a misstatement of the issue. It is not necessary when antedating a reference under 35 U.S.C. s 102(a) or (e) to establish a prior reduction to practice, constructive or actual, of all the subject matter falling within the claims. It is necessary only to establish a reduction to practice of sufficient subject matter to render the claimed invention obvious to one of ordinary skill in the art. In re Spiller, 500 F.2d 1170, 182 USPO 614 (Cust. & Pat. App. 1974). The \*274 majority errs, therefore, in seeking a description in appellants' parent and foreign priority applications to support the entire claimed subject matter as though these were the applications in which the claims appear. See In re Ziegler, 347 F.2d 642, 52 CCPA 1473, 146 USPQ 76 (1965). Appellants have clearly shown possession of enough of the invention to antedate Pfluger 1966 by establishing a prior constructive reduction to practice in their parent and foreign applications of specific embodiments disclosing concentrating to 50% and 36% total solids and by a broader disclosure of "25 to 60%."

Although the rejection of claim 1 arises in the context of an attempt to initiate an interference, the rejection is clearly under 35 U.S.C. s 102(a) or (e) and not under Rule 204(c), 37 CFR 1.204(c). Even if the rejection were under that rule, the substance of the rule's requirement for evidence sufficient to establish a prima facie case for a judgment of priority against Pfluger 1966 would be satisfied by the prior constructive reduction to practice of embodiments within claim 1 in appellants' parent

541 F.2d 257

· 'APR. 10. 2002

(Cite as: 541 F.2d 257, \*274)

and foreign applications. Hunt v. Treppschuh, 523 F.2d 1386, 187 USPQ 426 (Cust. & Pat. App. 1975); Fontijn v. Okamoto, 518 F.2d 610, 186 USPQ 97 (Cust. & Pat.App. 1975).

The majority cites In re Gemassmer, 319 F.2d 539, 51 CCPA 726, 138 USPQ 229 (1963), to support its decision on claim 1. It suffices to note that Gemassmer was decided more than a decade before In re Spiller, Hunt v. Treppschuh, and Fontijn v. Okamoto, supra.

I concur in the decision on claim 4 since appellants' parent and foreign applications are silent regarding final product temperature and a secondary heating step and, therefore, fail even as a constructive reduction to practice of the invention of claim 4.

I concur also in the decision on claims 19 and 20. but I do not find it necessary to hold, as the majority implicitly does, that "about 0.6" gm/cc excludes 0.5 gm/cc disclosed in the reference as the upper limit of merely a preferred range. Moreover, it is obvious from the reference that the process would work at a higher density than 0.5, although inferior results might be expected. My concurrence rests on

the requirement of claims 19 and 20 of a specific sequence of steps not suggested by the prior art, namely: providing a high density of about 0.6 to about 0.8 gm/cc, grinding to a fine particle size prior to freeze drying, freeze drying, and finally agglomerating the fine particles into larger particles. This achieves a "highly coloured product of regular particle size." There is no suggestion in the prior art of deliberately grinding to a fine size and then agglomerating to a larger size.

I dissent on claims 17, 18, and 29, because there is at least a prima facie relationship between product and foam densities. The board noted this by stating that "the freeze dried density of the coffee would be inherent in view of the same range of foam overrun density disclosed by Pfluger." Since the foam densities and other conditions disclosed by Pfluger for the process claimed are approximately the same, appellants should be required either to show that the reference does not achieve the same product densities or to establish criticality. Since they have not done so, I would affirm the rejection of claims 17, 18, and 29.

END OF DOCUMENT